INFLATABLE MULTI-CHAMBERED DEVICES AND METHODS OF TREATMENT USING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Ser. No. 13/473,545, filed May 16, 2012, which is a continuation of U.S. Ser. No. 11/761,069, filed Jun. 11, 2007, now issued as U.S. Pat. No. 8,236,057, which claims the benefit of U.S. Provisional Application 60/804,505, filed Jun. 12, 2006. Each of these references are hereby incorporated by reference in their entireties.

FIELD OF THE INVENTION

Example embodiments are generally directed to inflatable multi-chambered balloon devices, which may be useful for example, for the repair or replacement of spinal discs, as an inflation device to distract vertebral elements, as a cushioning device for joint replacement, or for cosmetic augmentation or restoration. Example embodiments are also directed to kits and systems that include such devices. Example embodiments are further directed to methods of treating a patient by inserting such devices into the patient.

BACKGROUND OF THE INVENTION

The intervertebral disc (IVD) permits articulation between adjacent elements of the spine. The disc includes an outer annulus fibrosis and an inner nucleus pulposus. In a healthy disc, the nucleus is a gel that transmits load and absorbs shock. Loads are constrained axially by the annulus fibrosis. Through degenerative processes and/or trauma, the annulus may fail and release the nucleus, which is then free to flow.

The posterior annulus is typically thinner than the anterior annulus, thus, making failures of the posterior annulus more common. When these failures occur, a variety of problems may arise. For example, the contents of the disc may impinge onto nerve roots and/or the spinal cord, resulting in pain and/or neurological deficits. IVD failures in the lumbar region of the spine are most common, but failures can occur at any level.

When disc failure occurs and pain is present, discectomy may be indicated to remove the impinging material. A 5-10% recurrence of painful extrusion may occur. Loss of the nucleus leads to kinematic changes to the segment and can accelerate weakening of the annulus and development of osteophytes at the vertebral endplates. This development of ectopic bone may lead to stenosis of the vertebral canal and detrimental changes to other articulating elements.

Injected liquids and implants have been proposed for insertion into a spinal disc space for different purposes. For example, some proposed systems include inflated balloons to distract disc space to restore lost height as preparation for an injected biomaterial or as an implant. Other systems include injecting liquids that harden or thicken in situ or hydrogel systems that expand upon exposure to water. The use of such devices, however, shares a common weakness, in that a failure of the device would tend to lead to rapid expulsion of the filler material, for example, through a pre-existing defect in the annulus. Such expulsion may create impingement in the same area that created a need for surgical intervention in the first place. For example, failure of such a device may lead to loss of material from the disc space which may then impinge on neural elements. The loss of any material from such

devices may lead to loss of disc height and detrimental changes to segment kinematics. Further, the arrangement of many of these devices would tend to lead to expulsion of the device itself, if deflated. Additionally, for devices constructed from a single chamber, the uneven compression of the disc in flexion and extension can result in improper loading of the disc space.

SUMMARY OF THE INVENTION

Example devices are generally directed to multi-chambered devices, which may be useful as intervertebral disc nucleus pulposus augmentation or replacement devices, as inflation devices to distract neighboring vertebral elements, as cushioning devices for joint replacement, or for cosmetic augmentation, reconstruction or restoration. Examples may further include devices that may be useful in mechanical systems where damping is required, or to position or maintain the position, or isolate machinery or structures. Example devices may include inflatable balloon devices, which include at least two chambers and a filling manifold. Example devices are adapted such that at least one of the chambers, and preferably multiple chambers, may be filled with a filler material, for example after insertion of the device into a patient.

Example embodiments are also directed to kits and systems that include inflatable devices. Such kits and systems may further include various other items, including, but not limited to filler material, tools or devices for inserting the inflatable devices into a patient, and/or tools or devices for inserting the filler material into at least one chamber of the inflatable devices, such as a high pressure gun.

Example embodiments are further directed to methods of treating a patient in need of treatment, by inserting into the patient a deflated device, and then inserting at least one filler material into at least one chamber of the inflatable balloon device. Such methods may also include prior removal of all or part of a disc or other material at or around the location in the patient where the device is to be inserted.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A and **1**B are top view and cross-sectional views respectively, of an inflatable device in accordance with example embodiments;

FIGS. **2**A and **2**B depict cross sectional views of an inflatable device in accordance with example embodiments;

FIGS. **3**A and **3**B depict a top view of an inflatable device in accordance with example embodiments;

FIG. **4** depicts a cross sectional view of an inflatable device in accordance with example embodiments;

FIG. **5** depicts a cross sectional view of an inflatable device in accordance with example embodiments;

FIG. **6** depicts a cross sectional view of example embodiments of devices having an encasement around the device;

FIGS. **7-12** depict cross sectional views of example embodiments of devices, in which chambers have oval cross sections and are oriented in different directions;

FIG. **13** depicts a cross sectional view of example embodiments of devices, in which chambers are essentially rectangular upon inflation;

FIG. **14** depicts a cross sectional view an inflatable device in accordance with example embodiments, in which chambers have various shapes upon inflation;

FIG. **15** depicts a cross sectional view of an inflatable device in accordance with example embodiments, in which the chambers have various shapes upon inflation;